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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,597	12/21/2001	Ian Robert Cottingham	0623.0730002/LBB/BJD	2450

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EXAMINER

PRIEBE, SCOTT DAVID

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,597

Applicant(s)

COTTINGHAM ET AL.

Examiner

Scott D. Priebe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,29 and 76-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28,29 and 76-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Paragraph numbering used below refers to the paragraph numbers assigned in published application US 2003/0167477.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Priority is claimed to application 10/019,153 filed 12/21/01, the same day the instant application was filed. Consequently, the '153 application is not a prior application under 35 USC 120, and the priority claim to the '153 application is improper. Priority is claimed to PCT/GB00/02459 indirectly through the '153 application, which is a 371 application of the PCT application. Consequently, the specific reference to the PCT application does not include the appropriate relationship between the instant application and the PCT application. The priority claim should be amended to delete reference to the '153 application, and to include the

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relationship between the instant application and the PCT application, e.g. continuation or continuation-in-part. For example:

The present application is a continuation of International Application No. PCT/GB00/02459, filed internationally on June 23, 2000, which was published in the English language under PCT Article 21(2) as WO 01/00855 on January 4, 2001, which claims the benefit of U.S. Provisional Application No. 60/147,819, filed August 10, 1999, and which claims priority to GB Application No. 9914733.2, filed June 23, 1999, the disclosures of all of which are incorporated herein by reference in their entireties.

Applicant's arguments filed 11/12/04 have been fully considered but they are not persuasive. Applicant is misinterpreting "entitled to the benefit of the filing date" in 35 USC 365(c). This means that for priority purposes, the effective filing date of the national application is actual filing date of the prior international application, not that the national application has an actual filing that is the actual filing date of the international application. Applicant is referred to the filing receipt for the '153 application, which indicates an actual filing date of 12/21/2001. It remains that the '153 application was filed on the same day as the instant application, and is not a "prior application" under 35 USC 120. If Applicant wishes more information on this issue, they are urged to call Special Programs Examiner William Dixon, Jr. at (571) 272-0512.

Information Disclosure Statement

The information disclosure statement filed 5/20/02 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein as reference AN2, EP 0590530 A2 has not been considered.

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References AP1, WO 92/22644, and AR1, Brignon et al., were considered only so far as the contents of their English abstracts, the remainder of these references not being in English.

Applicant's arguments filed 11/12/04 have been fully considered but they are not persuasive. First, this is not an objection, it is an indication of what was and what was not considered by the Examiner. The information disclosure statement did not indicate that reference AT12 was provided to fulfill the requirement for the explanation of relevance.

With regard to references AP1 and AR1, the IDS was not deemed improper due to inclusion of these references. The Examiner simply indicated the portions of these references that were considered and those portions that were not considered.

If Applicant is aware of information present in references AN2, AP1 or AR1 that is materially pertinent to the claimed subject matter, but is not evident from the English abstracts, it is Applicant's duty to bring that information to the attention of the Office.

Specification

The amendment to the specification is acknowledged, but could not be entered. The directions for entry of the amendments by reference to the published application do not comply with 37 CFR 1.121. The published application is not part of the application file, and the directions must refer to the specification present in the application file. Furthermore, the paragraphs in the specification were not numbered, so it is inappropriate to include paragraph numbers in the replacement paragraphs. It is noted that there is no need to replace "FIG. 2" with "FIG. 2A-D" on pages 23 or 26, although Applicant may make such a change if desired.

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The disclosure remains objected to because of the following informalities: The nucleotide and amino acid sequences shown in Fig. 1 are not identified by the assigned SEQ ID NO, as required by 37 CFR 1.821(d). This objection may be overcome amending either the 'Brief Description' of Fig. 1 (preferred) or Fig. 1 itself to include the assigned SEQ ID NOs.

Appropriate correction is required. The amendment filed 11/12/04 should be changed to remove paragraph numbers. The paragraphs numbered as 0057 and 0058 correspond to the two paragraphs in lines 1-4 on page 23 in the specification as filed. The paragraph numbered 0087 corresponds to the paragraph in lines 13-14 on page 26.

Claim Objections

Claim 79 is objected to because of the following informalities: recitation of "thereof of" in part (i) is redundant and grammatically incorrect. The term "thereof" should be deleted. Appropriate correction is required.

Claim 79 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 28 requires that the peptide be one not naturally occurring in milk. However, as disclosed in Struck et al. (Horm. Metab. Res. 34: 460-465, 2002) calcitonin is naturally found in human milk, e.g. Table 3. Consequently, claim 28 excludes at least calcitonin, which is listed in claim 79. It is unclear whether the other proteins listed are or are not found naturally in milk.

Claim Rejections - 35 USC § 112

Claims 28, 29, and 76-80 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is directed to the inclusion of new matter in the amended and new claims.

Claim 28 (and its dependent claims) has been amended to recite “coding sequence operably linked to a regulatory sequence” and “peptide not naturally found in milk.” New claim 76, parts (b)-(d) limit the regulatory sequence to a 5’ untranslated region, a 3’ untranslated region, or an enhancer. Claim 79, part (i) limits the second segment to one that encodes “fragments” of the peptides listed in parts (a)-(h). Applicant indicates that these limitations are supported by original claims 7 and 28; Figure 1; Examples 1, 2, and 3; and paragraphs 0018, 0020, 0025, and 0050 (referring to the published application). However there is no explicit or implicit support for these limitations in the indicated parts of the original disclosure, or any other parts of the original specification. There is no evidence of record that Applicant had contemplated or been in possession of the embodiments represented by these amended and new claims.

With respect to “regulatory sequence” recited in claims 28 and 76-78, and the alternate regulatory sequences listed in parts (b)-(d) of claim 76, the term “regulatory sequences” appears only in paragraphs 0020 and 0026 in relation to the possibility that differences in regulatory

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sequences might explain the improved expression in milk when lysozyme was included as a fusion partner. This is not a description of what the invention should include other than lysozyme as a fusion partner. Paragraph 0050 constitutes the only generic description of non-translated sequences to be included in the transgene for regulating expression of the fusion protein. It teaches a “DNA sequence which is suitable for directing the production to the milk of transgenic animals carries a 5' promoter region derived from a naturally derived milk protein” and (not or), optionally, at “the other end of the fusion protein construct a suitable 3' sequence, preferably also derived from a naturally occurring milk protein may be added.” Paragraph 0025 discusses comparing expression of lysozyme and α -lactalbumin from constructs comprising the same promoter and 3' untranslated region (both from the β -lactoglobulin gene, which is a “naturally derived milk protein”). Paragraphs 0078, 0088 and 0106 each describe specific embodiments of the invention where the transgene comprised “a 4.2 kb region comprising the ovine β -lactoglobulin (BLG) promoter and 5' untranslated region (UTR)”, which are the only places in the original specification where the term “5' untranslated region” is used. Nowhere does the specification describe any generic or specific transgene construct that does not at least comprise a promoter of a gene encoding “a naturally derived milk protein”. A “suitable 3' sequence” is taught as an optional addition to a construct that has a promoter of a gene encoding “a naturally derived milk protein” (¶ 0050). The term “enhancer” appears only once in the specification at ¶ 0025 in reference to the possibility that the coding sequence for lysozyme contains an enhancer. Nowhere does the specification describe using an enhancer as a regulatory sequence for expression of the fusion protein, either alone or in addition to a promoter of a gene encoding “a naturally derived milk protein”.

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To overcome this part of the rejection, “regulatory sequence” in claim 28 should be replaced with --promoter from a gene encoding a naturally derived milk protein--. Claims 76 and 77 should be cancelled. Claim 78 should depend from claim 28, and “regulatory sequence” should be replaced with --promoter--.

With respect to recitation of “peptide not naturally found in milk” in claim 28. None of the parts of the original specification indicated by Applicant indicate that peptides not naturally found in milk should be excluded from the invention. Furthermore, there is no evidence of record that one or more of the peptides listed in claim 79 would not be found naturally in milk, even if at very low levels. As disclosed in Struck et al., at least calcitonin is naturally found in milk.

To overcome this part of the rejection, the phrase “not naturally found in milk” should be deleted. In order to avoid the prior art cited in the previous action where the fusion protein was a signal peptide of a milk protein fused to lysozyme, “comprises a first” in line 3 of claim 28 could be replaced with --comprises, in order, a first--, which is supported by Fig. 1, for example. Alternatively, “not naturally found in milk” could be replaced with --other than a protein leader sequence--, which is supported by paragraph 0050 in discussing the inclusion of protein leader sequences to direct secretion of the fusion protein into the milk.

With respect to the limitation in claim 79, part (i) that the peptide may be a fragment of a peptide listed in parts (a) to (h), the term “fragment” is not used in the original specification, and the term “fragments” appears once in ¶ 0011 describing what milk contains. Nowhere does the original specification suggest that the peptide to be produced was a “fragment” of any known peptide, much less one of the peptides listed in parts (a) to (h) of claim 79.

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To overcome this part of the rejection, Claim 79 should be amended by inserting "and" at the end of step (g), and deleting "and (i) fragments thereof of any of (a) through (h)."

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

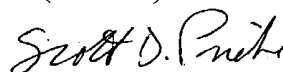
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER